

EXHIBIT B-8

MDD CAPA Database Export

CAPA Number: CAPA-002157

CAPA Detail

CAPA Number	CAPA-002157
Created Date	1/30/2013 12:00:00 PM
CAPA Title	CAPA130022: Repeat NCR's for Temporary Positioning Aide.
CAPA Description	Repeat non-conformances for particles found on a temporary positioning aide during the assembly process for TVT at the Neuchatel Manufacturing plant.
OpCo : Site	Ethicon : Neuchatel
CAPA Originator	Lowe, Carmel (43005386)
CAPA Type	Corrective
CAPA Owner	Journot, Vincent (77150115)
Current Phase	Final Approval
Phase Due Date	5/1/2014 9:59:59 PM
Phase Assign To	Bolton, Ken (335551)
Phase Assign To	Poulot, Stephane (79090201)
Days Open	455
Investigation Approval Completion Date	11/21/2013 11:03:03 AM
CAPA Scope	Product Process : Assembly or Manufacturing Defect
Product Family	TVT; TVT ABBREVO; TVT Exact; TVT Obturator; TVT Secur
Business Unit	Ethicon : Gynecare
Franchise/Supply Chain owned	Supply Chain
CAPA Associated with	CAPA Review Board / Data Review
CAPA Data Source	Nonconformance
CAPA Reference Info	Refer to ETQ CAPA Go Live Protocol No. 100133718 Rev 2.0, CRB conducted 28 Jan 2013 -Neuchatel Site, NCR12-10293, NCR12-10960, NCR13-00712, NCR13-01136
Is Immediate Correction Required	Yes
Immediate Correction Description	Immediate corrections were lead by NCR activities in addition to introduction of statistically based specific defects audits (SDA per WI-EMSP007) initiated and performed on all batches since detection of first NCR12-10293 (11/22/2013)
Is the Issue Supplier Related	No
Are Other Site Affected	No
Rationale Other Site Affected	No internal manufacturing site is impacted as the manufacturing process is unique to the Neuchatel site.
Is Investigation Plan Required	No
Risk Level	Medium

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Document Risk Assessment	This is a Class I defect and was not anticipated. 10.8% (7 impacted batches on 65 manufactured batches between the November 22th, 2012 and January 30th, 2013. See attachment : CAPA130022_Defective_perventage_justification.pdf). Microbiological contamination from positioning aids referenced in risks analyzes didn't concern potential contamination by particles. It's only microbiological contamination evaluated by regular test's methods on products and surfaces.
Reference Documentation	GDS-PFMEA-100951 revB, GDS-PFMEA-100177 revB, GDS-PFMEA-100178 revJ, GDS-PFMEA-100932 revB. All documents are effective from November 5th, 2012.
Summary of Investigation	Refer to FM-0001222_Failure_Investigation-CAPA130022-root_causes_analysis.pdf
Root Cause Classification	Material : Incorrect specification (Design); Method / Process : Procedures not adequately defined
Root Cause Methodology(s)	Cause and Effect Diagram (Ishikawa, Fishbone, 5M + 1)
Root Cause Description and Rationale	1. No material specification for this positioning aid is in place (Linked to Material: Incorrect Specification (design))2. Manufacturing aids are not captured within the Neuchâtel change control process (linked to method/process: Procedures not adequately defined)
Is Action Plan Required	Yes
Action Classification	Correction
Action Classification	Corrective
Root Cause Being Addressed with this Action	Material : Incorrect specification (Design)
Root Cause Being Addressed with this Action	Method / Process : Procedures not adequately defined
Effectiveness Owner	Journot, Vincent (77150115)
Effectiveness Action Expected Completion Date	4/18/2014 12:00:00 PM
Eff Mon Modified Due Date	4/18/2014 12:00:00 PM
Effectiveness Monitoring Data source	Nonconformance
Effectiveness Monitoring Action plan	Effectiveness of this CAPA shall be measured on the number of NCR's raised for particles attributed to the positioning sheaths holder in the period of 3 months from the completion of the action of implementation of the new positioning sheaths holder. Baseline data (7 batches with at least 3 parts with particles attributed to positioning sheaths holder on 65 batches manufactured between 22-Nov-12 and 30-Jan-13.
Describe the quantifiable and measureable Pass/Fail Criteria	A decrease from a baseline of 10.8% of impacted batches to 0.25% of impacted batches during the 3 month effectiveness monitoring time period.
Date Effectiveness Monitoring Action Completed	4/11/2014 12:00:00 PM

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Effectiveness Action Results

Time frame selection: The new analysis of percentage defective rate after monitoring phase is realized on data from the January 15th, 2014 to April 11th, 2014. Start point is the date of implementation of new plastic sheaths holders in manufacturing area. End point is the end of effectiveness monitoring phase schedule on ETQ system. Data selection: Data selected are number of NCR raised for particles attributed to the positioning sheaths holder in the time frame and the number of batches manufactured in same time frame. During this time frame, an extract of ERP system shows that 79 batches (typical lot size : 714 parts with 1 plastic sheath holders per part) of TVT products were manufactured and 0 NCR attributed to the positioning sheaths holders were opened. (confirmed by NCR site lead) Defective rate calculation: Based on data within the time frame, new percentage defective rate is 0%, which is below 0.25%. Conclusion: The decrease of defective percentage rate from a baseline of 10.8% of impacted batches to 0.25% is confirmed.

EM Action: Was this Effective?

Yes

Was the CAPA Effective?

Yes

Summary/Rationale

Zero non conformances were opened during the effectivity monitoring period of 3 months, therefore CAPA is effective.

QA Approver

Poulot, Stephane (79090201)

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Do You Approve?

Yes

Status

On-Time

Action Plan Details

Action Plan Number

AP-008430

Created Date

11/21/2013 11:03:03 AM

Action Owner

Journot, Vincent (77150115)

Current Phase

Complete

Phase Due Date

1/15/2015 10:59:59 PM

Assign To

Journot, Vincent (77150115)

Due Date

1/15/2014 12:00:00 PM

Function Area where the Issue Resides

Operations : Plant Engineering

Action Status

On Time

Action Type

Corrective

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Action	Release approved material specifications and Introduce new positioning sheath holder into production.
Root Cause associated with this Action	Method / Process : Procedures not adequately defined
Action Results	Material specification 100131722 rev 1, drawing 100131715 rev A, checklist 100134182 rev 1 were released by change order 100134167 in adaptiv. New positioning sheath holders were introduced in production on January, 15th 2014 following training of associate to updated work instructions (TM-TME0110 rev2, WI-FT0094 rev22, WI-FT0507 rev8, WI-FT0149 rev12 & WI-FT0096 rev8) released by change order 100144671 in Adaptiv.
Number of extension requested	0
Completion Date	1/15/2014 8:58:50 AM
Document the Verification and Validation	Refer to change order 100134167 in Adpativ released on December, 2nd 2013 for Material Specifications. Refer to change order 100144671 in Adpativ released on January, 15th 2014.
Functional Area Approver	Bolton, Ken (335551)
QA Approver	Yuill, Colin (72005740)
Do You Approve?	NA
Action Plan Number	AP-008430
Created Date	11/21/2013 11:03:03 AM
Action Owner	Journot, Vincent (77150115)
Current Phase	Complete
Phase Due Date	1/15/2015 10:59:59 PM
Assign To	Journot, Vincent (77150115)
Due Date	1/15/2014 12:00:00 PM
Function Area where the Issue Resides	Operations : Plant Engineering
Action Status	On Time
Action Type	Corrective
Action	Release approved material specifications and Introduce new positioning sheath holder into production.
Root Cause associated with this Action	Material : Incorrect specification (Design)
Action Results	Material specification 100131722 rev 1, drawing 100131715 rev A, checklist 100134182 rev 1 were released by change order 100134167 in adaptiv. New positioning sheath holders were introduced in production on January, 15th 2014 following training of associate to updated work instructions (TM-TME0110 rev2, WI-FT0094 rev22, WI-FT0507 rev8, WI-FT0149 rev12 & WI-FT0096 rev8) released by change order 100144671 in Adaptiv.
Number of extension requested	0
Completion Date	1/15/2014 8:58:50 AM
Document the Verification and Validation	Refer to change order 100134167 in Adpativ released on December, 2nd 2013 for Material Specifications. Refer to change order 100144671 in Adpativ released on January, 15th 2014.

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Functional Area Approver	Bolton, Ken (335551)
QA Approver	Yuill, Colin (72005740)
Do You Approve?	NA
Action Plan Number	AP-008429
Created Date	11/21/2013 11:03:02 AM
Action Owner	Journot, Vincent (77150115)
Current Phase	Complete
Phase Due Date	11/28/2014 10:59:59 PM
Assign To	Journot, Vincent (77150115)
Due Date	11/28/2013 12:00:00 PM
Function Area where the Issue Resides	Operations : Plant Engineering
Action Status	On Time
Action Type	Corrective
Action	Define and identify concerned manufacturing aids
Root Cause associated with this Action	Method / Process : Procedures not adequately defined
Action Results	A cross functional team (which included Quality Engineer, production, Engineering) defined what a manufacturing aid was in terms of identifying manufacturing aids on site. Definition established was: manufacturing aid is a tool used during a manufacturing process in direct contact with products which could influence product quality, but it is not manufacturing equipment, an inspection gage or measurement equipment. Based on this definition a review was performed by the same cross functional team to identify the manufacturing aids on site.
Number of extension requested	0
Completion Date	11/28/2013 10:32:45 AM
Document the Verification and Validation	Definiton of manufacturing aids was added to SCP-EPG034 rev 35 through change order 100169449 released on November 28th, 2013 (See action 1). The Change order 100169449 also contains the list of manufacturing aids identified.
Functional Area Approver	Bolton, Ken (335551)
QA Approver	Yuill, Colin (72005740)
Do You Approve?	NA
Action Plan Number	AP-008428
Created Date	11/21/2013 11:03:02 AM
Action Owner	Journot, Vincent (77150115)
Current Phase	Complete
Phase Due Date	11/28/2014 10:59:59 PM
Assign To	Journot, Vincent (77150115)
Due Date	11/28/2013 12:00:00 PM
Function Area where the Issue Resides	Operations : Plant Engineering

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Action Status	On Time
Action	Create or update applicable Neuchatel change control procedure(s) to manage manufacturing aids
Action Type	Correction
Root Cause associated with this Action	Method / Process : Procedures not adequately defined
Action Results	SCP-EPG034 Rev 35 CHANGE CONTROL PROCEDURE was updated by change order 100169449 in Adaptiv to include manufacturing aids in scope of change control procedure SCP-EPG034. A definition and requirements for manufacturing aids was added to procedure SCP-EPG034.
Number of extension requested	0
Completion Date	11/28/2013 10:31:09 AM
Document the Verification and Validation	Refer to change order 100169449 in Adpativ released on November 28th, 2013
Functional Area Approver	Bolton, Ken (335551)
QA Approver	Yuill, Colin (72005740)
Do You Approve?	NA
Record Order	0
Phase	Originate
Assign To	Lowe, Carmel (43005386)
Submitted Date	10/15/2013 11:56:12 AM
Phase Due Date	10/17/2013 9:59:59 PM
Completed Date	10/15/2013 12:14:03 PM
Record Order	1
Phase	Investigation
Assign To	Lowe, Carmel (43005386)
Submitted Date	10/15/2013 12:14:03 PM
Phase Due Date	11/20/2013 10:59:59 PM
Completed Date	11/18/2013 4:21:59 PM
Record Order	2
Phase	Investigation
Assign To	Journot, Vincent (77150115)
Submitted Date	11/18/2013 4:21:59 PM
Phase Due Date	11/20/2013 10:59:59 PM
Completed Date	11/19/2013 6:31:59 AM
Record Order	3
Phase	Approval
Assign To	Bolton, Ken (335551)
Submitted Date	11/19/2013 6:31:59 AM
Phase Due Date	11/26/2013 10:59:59 PM
Completed Date	11/21/2013 8:32:35 AM

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Record Order	3
Phase	Approval
Assign To	Yuill, Colin (72005740)
Submitted Date	11/19/2013 6:31:59 AM
Phase Due Date	11/26/2013 10:59:59 PM
Completed Date	11/21/2013 8:32:35 AM
Record Order	4
Phase	Approval
Assign To	Bolton, Ken (335551)
Submitted Date	11/21/2013 8:32:35 AM
Phase Due Date	11/26/2013 10:59:59 PM
Completed Date	11/21/2013 11:03:01 AM
Record Order	5
Phase	Implementation
Assign To	Journot, Vincent (77150115)
Submitted Date	11/21/2013 11:03:01 AM
Phase Due Date	1/15/2014 10:59:59 PM
Completed Date	11/22/2013 10:06:50 AM
Record Order	6
Phase	Originate
Assign To	Lowe, Carmel (43005386)
Submitted Date	11/22/2013 10:06:50 AM
Phase Due Date	11/24/2013 10:59:59 PM
Completed Date	11/22/2013 10:09:47 AM
Record Order	7
Phase	Investigation
Assign To	Journot, Vincent (77150115)
Submitted Date	11/22/2013 10:09:47 AM
Phase Due Date	12/28/2013 10:59:59 PM
Completed Date	11/22/2013 10:12:19 AM
Record Order	8
Phase	Implementation
Assign To	Journot, Vincent (77150115)
Submitted Date	11/22/2013 10:12:19 AM
Phase Due Date	1/15/2014 10:59:59 PM
Completed Date	1/27/2014 9:01:32 AM
Record Order	9
Phase	Effectiveness Monitoring
Assign To	Journot, Vincent (77150115)
Submitted Date	1/27/2014 9:01:32 AM

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Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/22/2014 10:22:11 AM
Record Order	10
Phase	Effectiveness Monitoring
Assign To	Poulot, Stephane (79090201)
Submitted Date	4/22/2014 10:22:11 AM
Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/22/2014 10:25:16 AM
Record Order	11
Phase	Effectiveness Monitoring
Assign To	Journot, Vincent (77150115)
Submitted Date	4/22/2014 10:25:16 AM
Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/22/2014 1:54:07 PM
Record Order	12
Phase	Effectiveness Monitoring
Assign To	Poulot, Stephane (79090201)
Submitted Date	4/22/2014 1:54:07 PM
Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/24/2014 3:01:51 PM
Record Order	12
Phase	Effectiveness Monitoring
Assign To	Journot, Vincent (77150115)
Submitted Date	4/22/2014 1:54:07 PM
Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/24/2014 3:01:51 PM
Record Order	13
Phase	Effectiveness Monitoring
Assign To	Journot, Vincent (77150115)
Submitted Date	4/24/2014 3:01:51 PM
Phase Due Date	4/18/2014 9:59:59 PM
Completed Date	4/24/2014 3:03:09 PM
Record Order	14
Phase	Final Approval
Assign To	Poulot, Stephane (79090201)
Submitted Date	4/24/2014 3:03:09 PM
Phase Due Date	5/1/2014 9:59:59 PM
Record Order	14
Phase	Final Approval
Assign To	Bolton, Ken (335551)

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Submitted Date	4/24/2014 3:03:09 PM
Phase Due Date	5/1/2014 9:59:59 PM